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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,749	10/23/2001	Paul Lehmann	9524	7514

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HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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EXAMINER	
NICHOLS, CHRISTOPHER J	

ART UNIT	PAPER NUMBER
1647	7

DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/047,749	LEHMANN, PAUL	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,16 and 19-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15,16 and 19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09381248* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Amendment filed 13 May 2003 (Paper No. 6) has been received and entered in full.

2. Claims 17 and 18 have been cancelled, claims 28 and 29 have been added, and claims 15, 19, and 20 have been amended.

3. Claims 15, 16, and 19-29 are currently under examination.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

5. The objection to the Specification as set forth at ¶5-6 pp. 3 in the previous Office Action (Paper No. 4, 15 January 2003) is *withdrawn* in view of Applicant's amendments (Paper No. 6, 13 May 2003).

6. The rejections of claims **15**, **16** and **19-27** under 35 U.S.C. §112 ¶2 as set forth at ¶7-8 pp. 3-4 in the previous Office Action (Paper No. 4, 15 January 2003) are *withdrawn* in view of Applicant's amendments (Paper No. 6, 13 May 2003).

7. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "Unit" in claims 15, 19, and 20 is used by the claim to mean "amu", while the meaning is open

to interpretation. The term is indefinite because the specification does not clearly redefine the term.

8. However, it is of note that US 2002/0160956 A1 (31 October 2002) Lehmann et al. states:

> "...the abbreviation 'IU' can also be used in place of the abbreviation 'U' for 'International Units'..."

9. Since US 2002/0160956 shares a common inventor with the instant application, the Examiner accepts the equivalency of "U" as used by the Applicant with the art-accepted term, "IU".

10. The rejections of claims **17** and **18** under 35 U.S.C. §112 ¶2 as set forth at ¶7-8 pp. 3-4 in the previous Office Action (Paper No. 4, 15 January 2003) are *moot* in view of Applicant's cancellation of said claims (Paper No. 6, 13 May 2003).

11. The rejections of claims **17** and **18** under non-statutory obvious-type double patenting as set forth at ¶10-16 pp. 4-6 in the previous Office Action (Paper No. 4, 15 January 2003) are *moot* in view of Applicant's cancellation of said claims (Paper No. 6, 13 May 2003).

12. The rejection of claim **24** under 35 U.S.C. §112 ¶2 as set forth at ¶9 pp. 4 in the previous Office Action (Paper No. 4, 15 January 2003) is *withdrawn* in view of Applicant's arguments (Paper No. 6, 13 May 2003).

13. The rejection of claims **15, 16,** and **19-27** under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1-34 of U. S. Patent No. 6333306 in view of Mercuriali and Inghilleri (1995) "Iron administration to optimize the effect of r-HuEPO in the surgical setting." Erythropoiesis: New Dimensions in the Treatment of Anemia **6**: 67-76 for the reasons as set forth in at ¶11-16 pp. 5-6 of the previous Office Action

(Paper No. 4, 15 January 2003) are *withdrawn* in view of Applicant's amendments (Paper No. 6, 13 May 2003).

New Rejections

Obvious-Type Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims **15, 16, 19-27,** and newly added claims **28** and **29** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6372715 B1 (16 August 2002) Kaltwasser and Lehmann in view of Mercuriali and Inghilleri (1995) "Iron administration to optimize the effect of r-HuEPO in the surgical setting." Erythropoiesis: New Dimensions in the Treatment of Anemia **6**: 67-76 taken with Pincus *et al.* (August 1990) "Multicultural Study of Recombinant Human Erythropoietin in Correction of Anemia in Rheumatoid Arthritis." The American Journal of Medicine **89**(2): 161-168. Although the claims are not identical, they are not patentably distinct from each other because the claims of US 6372715 describes a method for the treatment of the activity of

rheumatic disease in patients comprising administering to said patient suffering from said rheumatic disease a combination therapy comprising a first component consisting of 250 to 15,000 U of an erythropoietin preparation and a second compound, consisting of an amount of a physiologically compatible iron preparation, which iron preparation administering to said patient from 1 to 40 mg of iron ions, thus meeting the limitations of claim 15 (Col. 11-12; claims 1-11).

15. Regarding iron dosages, the art recognizes that it is important to provide adequate supplemental iron during erythropoietin treatment. Mercuriali and Inghilleri (1995) provide a method by which these dosages can be determined for the treatment thus meeting the limitations of Claims 15-27 (pp. 73 "Iron Supplementation Strategies").

16. Regarding iron preparations and iron complexes, US 6372715 teaches the use of physiologically compatible iron preparations, especially those having a molecular weight of between 30,000 and 100,000 D, including Fe(III)saccharate and Fe(III)gluconate thus meeting the limitations of claims 22-27 (Col. 6-8).

17. While the claims of US 6372715 are directed to treating rheumatic disease in patients, Pincus *et al.* teaches that anemia is a frequent extra-articular manifestation of rheumatoid arthritis, a rheumatic disease. Pincus *et al.* teach the treatment of patients with rheumatoid arthritis with recombinant erythropoietin resulting in creased hematocrits leading to an alleviation of the anemia (Figure 1 and 2). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the treatment regiment as laid out in the claims with the dosages of US 6372715 and the iron preparations as taught by Mercuriali and Inghilleri (1995). The adjustment the amounts of erythropoietin and iron supplements would improve the erythropoietin therapy (Mercuriali and Inghilleri, 1995).

18. A person of ordinary skill in the art at the time of the invention could reasonably expect success because the combination of iron supplements and erythropoietin are known in the art at the time of the invention (Mercuriali and Inghilleri, 1995: 68 "Dosage of r-HuEPO").

19. The person of ordinary skill in the art would have been motivated to make those modifications because of the danger of iron toxicity and the need to carefully tailor iron administration during erythropoietin therapy to insure sufficient iron is present to meet the demands of increased hematopoiesis, in anemia, whether alone or in conjunction with treating a rheumatic disease. The modification of the amounts and administration regiment at the time of the invention was seen as a desirable method to improve the effectiveness of erythropoietin therapy.

Summary

20. Claims **15, 16,** and **19-27** as well as newly added claims **28** and **29** are hereby rejected.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:00AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Elizabeth C. Kemmerer

CJN
June 20, 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER